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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,367	06/23/2005	Julia Hurwitz	SJ-02-0015A	6654

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,367	HURWITZ ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ___.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed October 25, 2007 is acknowledged and entered. Claims 6-10 and 12-15 are pending and under examination.

Specification

2. The specification remains objected to because the first paragraph on page 1 should include a reference to PCT/US04/00635. Alternatively, Applicant may reference the PCT in an application data sheet in lieu of amending the specification.

Claims Summary

3. The claims are drawn to a method for inducing a B-cell immune response in a human subject against systemic human parainfluenza virus (HPIV-1) infection comprising administering a composition comprising a Sendai virus and a pharmaceutically acceptable carrier via intranasal administration. The specification defines Sendai virus as a mouse parainfluenza virus which is the murine homologue of HPIV-1, see paragraph [0009] of the specification. The composition is in the form of a spray, one or more droplets, or an aerosol. The human is less than 10 years old, less than 5 years old, or less than 1 year old. The amount of Sendai virus composition administered is between $1x10^5$ to $1x10^8$ plaque forming units (pfu).

Claim Objections

4. (*New Objection*) Claim 15 is objected to for a minor informality. Claim 15 contains a typo in the phrase, "The method of claim 6 herein said effective immunizing amount". Instead of "herein", the claim should recite, "wherein".

(*New Objection*) Claims 7, 9 and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, specifically, claim 6. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

- Claim 7 does not appear to further limit claim 6 from which it depends. Claim 7 indicates that the composition is administered to the upper respiratory tract. If the composition is administered intranasally, it necessarily is administered to the upper respiratory tract.
- Claim 9 fails to further limit claim 6 from which it depends. Claim 9 indicates a variety of administration routes in addition to the intranasal administration route.
- Claim 10 fails to further limit claim 6 which it depends. Claim 10 indicates that a variety of immune responses are induced in addition to a B-cell response.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-10 and 12-15 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling for the entire scope of the claims, for reasons of record. Applicant's amendments to the claims are acknowledged and have addressed nearly all of the aspects of the rejection, however, the remaining term "an effective immunizing amount" indicates a protective effect. Suggested language is "an effective amount", or "an amount effective for inducing the B-cell immune response". The term "immunizing amount" indicates a prophylactic effect which is not enabled by the specification for reasons of record.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurwitz *et al.* (*Vaccine*, 1997, 15(5):533-540, "Hurwitz"). The claims are summarized above. Note that this rejection is made with respect to the enabled aspect of the claims, not the entire scope which encompasses non-enabled embodiment (see rejection under 35 U.S.C. 112, first paragraph).

Hurwitz discloses the administration of an intranasal Sendai virus composition that protected African green monkeys from infection with HPIV-1 (abstract). Monkeys were inoculated with Sendai (mouse PIV1, Enders strain) in an amount of 7.6×10^7 EID_{50}, and then challenged with HPIV-1 (C35 strain), see page 534, "RESULTS" section. HPIV-1 was not detectable in the experimental monkeys following challenge with HPIV-1, while the control

monkeys (receiving no Sendai virus composition and exposed to HPIV-1) became infected with HPIV-1 (page 536, columns 1 and 2). Hurwitz discloses that unmanipulated Sendai virus is an effective vaccine against HPIV-1 in a primate model and may constitute a practical vaccine for human use (abstract). Therefore, the embodiments of claims 6-10 and 15 are anticipated by the prior art.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being obvious over Hurwitz *et al.* (*Vaccine*, 1997, 15(5):533-540, "Hurwitz"). The claims are summarized above, as are the teachings of Hurwitz. Note that this rejection is made with respect to the enabled aspect of the claims, not the entire scope which encompasses non-enabled embodiment (see rejection under 35 U.S.C. 112, first paragraph).

Although Hurwitz does not name the specific ages of the young children that are affected by HPIV-1 infection and disease (Hurwitz, abstract, first sentence, and page 533, column 1, first sentence), it would have been obvious to administer Hurwitz's composition to children that are under the age of 10, 5 and less than a year old, since HPIV-1 is known to infect and cause disease in children, even infants that have "croup" (Hurwitz, page 533, column 1, first sentence). Given what is known regarding the patient population of HPIV-1, it would have been obvious to

administering Hurwitz's composition to children under 10 years old with a reasonable degree of predictability.

Response to Arguments

8. Applicant's arguments regarding the 102 and 103 rejections have been carefully considered but fail to persuade. Applicant argues that the administration of Sendai virus to humans has been rejected by experts in the field due to concerns that Sendai virus may cause disease in humans or may not induce cross-reactive antibodies to HPIV-1. Applicant cites Skiadopoulous *et al.* (*Virology*, 2002), Girard *et al.* (*Vaccine*, 2005), and Bukreyev *et al.* (*J. Virol.*, 2006) as evidence of a general sentiment in the art that use of Sendai in humans is not entirely acceptable given various factors.

In response to Applicant's arguments, the Office has considered the references that Applicant refers to, as well as the subject matter now claimed: inducing a B cell immune response. The Office acknowledges that there are differing opinions in the art regarding the use of Sendai virus as a means of inducing an immune response in humans against HPIV-1. Despite the opinions of those of skill in the art cited in the references submitted by Applicant, Hurwitz (also one of skill in the art) discloses that unmanipulated Sendai virus is an effective vaccine against HPIV-1 in a primate model and may constitute a practical vaccine for human use (abstract). Hurwitz is evidence that one of ordinary skill in the art would have had a *reasonable* expectation of success that administration of Sendai virus to a human would induce at least an antibody response against HPIV-1. Therefore, the rejections are maintained for reasons of record.

Conclusion

9. No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off,. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 1-14-2008
Primary Examiner, TC1600